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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,936	06/16/2006	Pascal LeFrancois	34930160PUS1	8111
2292	7590	09/28/2007	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH			YU, GINA C	
PO BOX 747			ART UNIT	
FALLS CHURCH, VA 22040-0747			PAPER NUMBER	
			1617	
			NOTIFICATION DATE	
			DELIVERY MODE	
			09/28/2007	
			ELECTRONIC	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

## Office Action Summary

**Application No.**

10/565,936

**Applicant(s)**

LEFRANCOIS ET AL.

**Examiner**

Gina C. Yu

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____                                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/26/06 08/02/06</u>   | 6) <input type="checkbox"/> Other: ____                           |

## **DETAILED ACTION**

### ***Claim Objections***

Claim 25 is objected to because of the following informalities: claim 25 has a typographical error in reciting the base claim. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 is rejected, as it is not clear what applicants mean by "the proportion".

Is the proportion is in the volume or in weight?

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 12-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bohn (US 4957730) in view of Wohlrab et al. (US 5346692).**

Bohn discloses a nail varnish comprising an antimycotic compound which is at least one 1-hydroxy-2-pyridone of the formula (I) of instant claim 1 and a water-insoluble film-forming substance. See abstract. The reference teaches adding customary

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cosmetic agents, specifically, keratolytic and/or keratoplastic agents such as ammonium sulfite, esters and salts of thioglycolic acid, urea, allantoin, enzymes and salicylic acid.

See col. 3, lines 51 – 62. See instant claim 12 b). The amount of the active compounds is in an amount of 2-80%, preferably 10-60 and in particular 20-40 % by weight of non-volatile components, which includes film-forming agents, pigments and plasticizers and other non-volatile additives as well as the active compound. See col. 2, lines 35 – 49.

See instant claims 18-21. While the weight amounts of urea as taught by Wohlrab are based on the weight of the non-volatile components, the combined teachings of the references provide general conditions of the present claims, examples 12 and 13 illustrate using 2% by weight of 1-hydroxy-4-methyl-6- (2,4,4-trimethylpentyl)-2-pyridone and 12 % by weight of 1-hydroxy-4-methyl-6-cyclohexyl-2-pyridone, which respectively make up about 2.2 % and 16.9 % by weight of the volatile materials of the compositions. See instant claim 12 a), 13-16. Example 13 also uses 4 % of 1-hydroxy-4-methyl-6-cyclohexyl-2-pyridone, contains polyvinyl acetate, meeting instant claim 22. The film-forming agents of instant claim 22 are also disclosed in col. 3, lines 9 – 33.

The solvents of instant claims 23-24 are also discussed in col. 3, lines 34-50.

Bohn does not specifically mention the amount of the keratolytic agents to be used in the formulations. Although the reference teaches using low alcohols as solvents, the reference does not specifically mention the water content of the nail varnish formulations.

Wohlrab teaches antimycotic nail varnish compositions for treating onychomycosis, comprising of a film-forming agent, antimycotically active substance,

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preset in the amount of 5-30 % based on the weight of the non-volatile component, and urea, present in the amount of 15-60 % based on the weight of the non-volatile components. The addition of urea to the nail varnish is said to improve the antimycotic effects without affecting the healthy parts of the nail from substantial keratolysis.

Example 1 teaches 0.28 g of urea used in 10 g of solvents, thus meeting the weight amount of urea as required by instant claim 1 b). As for instant claim 24-25, the reference teaches in Examples 1 and 2 that the optimum solvent system contains ethanol with 90 vol. % ethanol with 10 vol. % water.

Given the teaching of Bohn to incorporate keratolytic agents to the antimycotic nail varnish formulations, it would have been obvious that a skilled artisan would have been motivated to look for other prior arts, such as Wohlrab, for a more specific teaching on the amount of the keratolytic agent that can be used in the nail varnish formulation. Wohlrab would have motivated the one skilled in the art to incorporate urea in the amount as taught by the reference, because 1) both Bohn and Wohlrab teach adding urea to the nail varnish formulations having antimycotic agents; and 2) Wohlrab teaches that urea aids in the keratolytic effect of antimycotic agent without affecting the healthy parts of the nail, and also teaches the specific amount of urea to use.

### ***Conclusion***

No claims are allowed.

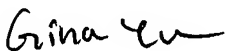
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-8605.

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The examiner can normally be reached on Monday through Friday, from 8:00AM until 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Gina C. Yu  
Patent Examiner